

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ORTHOFLEX, INC. d/b/a/	§	
INTEGRATED ORTHOPEDICS, et al.,	§	
	§	
Plaintiffs-Counterdefendants,	§	
	§	Civil Action No. 3:11-CV-0870-D
VS.	§	(Consolidated with
	§	Civil Action No. 3:10-CV-2618-D)
	§	
THERMOTEK, INC.,	§	
	§	
Defendant-Counterplaintiff-	§	
Third-Party Plaintiff,	§	
	§	
VS.	§	
	§	
MIKE WILFORD,	§	
	§	
Consolidated defendant,	§	
	§	
VS.	§	
	§	
WMI ENTERPRISES, LLC, et al.,	§	
	§	
Third-Party Defendants.	§	

MEMORANDUM OPINION
AND ORDER

Plaintiffs-counterdefendants Orthoflex, Inc. d/b/a Integrated Orthopedics, Motion Medical Technologies, LLC, Wabash Medical Company, LLC, and consolidated defendant Mike Wilford (collectively, “plaintiffs”) object to the magistrate judge’s October 2, 2012 order denying their motion to sustain their objection and compel defendant-counterplaintiff-third-party plaintiff ThermoTek, Inc. (“ThermoTek”) to withdraw its designation of certain pages of OPWIL0006036-6902 as “confidential” under the protective order, and for

sanctions. Concluding that the magistrate judge erred in determining the motion under the Texas law of privilege rather than under the terms of the stipulated protective order, the court reverses the order, grants the motion to sustain plaintiffs' objection and to compel ThermoTek to withdraw its designation, and remands the matter to the magistrate judge to address plaintiffs' request for sanctions.¹

I

The instant objections and plaintiffs' underlying motion pertain to document OPWIL0006036-6902, which is a 510(k) (the "ThermoTek 510(k)") that ThermoTek submitted to the U.S. Food and Drug Administration ("FDA"). A 510(k) is a premarket notification submission required by the FDA for the purpose of determining whether a medical device to be marketed is at least as safe and effective as a legally-marketed device. *See* 21 C.F.R. § 807.92(a)(3) (2012). The ThermoTek 510(k) contains details about ThermoTek's medical technology for its VascuTherm System. ThermoTek maintains that pages 41, 824-849, and 1373 of the ThermoTek 510(k) are properly designated as "confidential" under the terms of the October 8, 2010 stipulated protective order ("Protective Order") entered in these consolidated cases.² Plaintiffs contend that the ThermoTek 510(k)

¹Although the briefing in this matter was filed under seal, the court has determined that this memorandum opinion and order should not be sealed.

²Two protective orders have been entered in these consolidated cases. On October 8, 2010—in the case that became No. 3:11-CV-0870-D—an agreed protective order was entered by a district judge of the Northern District of Illinois, before the case was transferred to this court. On April 20, 2011—in the case docketed in this court as 3:10-CV-2618-D—this court entered an agreed protective order with modifications made by the court. The

was publicly disclosed by the FDA and that the pages in question do not qualify as confidential under the Protective Order.

ThermoTek submitted the ThermoTek 510(k) before these consolidated lawsuits were filed. After a Freedom of Information Act (“FOIA”) request for the ThermoTek 510(k) was made in 2009, the FDA gave ThermoTek an opportunity to redact trade secret and confidential information before a releasable version was made available to the public. After ThermoTek requested redactions,³ the releasable version of the ThermoTek 510(k) (the “Releasable Version”) was printed on May 3, 2010 and became publicly available on the FDA website sometime thereafter. ThermoTek produced the ThermoTek 510(k), marked “confidential,” in September 2010.⁴ The Protective Order was entered on October 8, 2010. Plaintiffs obtained the Releasable Version from the FDA website in 2011. This version did not include all the redactions that ThermoTek had requested.

In January 2012 plaintiffs produced the Releasable Version to ThermoTek without designating it for confidential treatment under the Protective Order. In July 2012 plaintiffs took the deposition of ThermoTek’s Rule 30(b)(6) witness. During the deposition, they

court is referring here to the order filed on October 8, 2010.

³Plaintiffs dispute that ThermoTek actually requested redactions rather than simply marked some of the documents in question with the legend “proprietary.” The court need not decide this issue. For purposes of this decision, the result is the same whether the public disclosure was the fault of ThermoTek or the FDA.

⁴According to ThermoTek, “the parties agreed to maintain the confidentiality of that, and other, documents, pending the entry of the actual protective order.” ThermoTek Resp. 2.

marked the Releasable Version as an exhibit. The following day, ThermoTek designated the entire document as “confidential” under the Protective Order.

After the parties were unsuccessful in resolving their dispute concerning ThermoTek’s designation of the Releasable Version, plaintiffs filed their motion to sustain their objection and compel ThermoTek to withdraw its designation, and for sanctions. After the motion was filed, ThermoTek advised plaintiffs that, following discussions between ThermoTek and the FDA, certain pages from the Releasable Version had been removed from the FDA website and that pages 41, 824-849, and 1373 would continue to be designated as “confidential.” ThermoTek advised that all other pages of the Releasable Version had been de-designated. Plaintiffs’ motion therefore centered on pages 41, 824-849, and 1373, which had been removed from the FDA website and had been designated by ThermoTek as “confidential” under the Protective Order.

Following a hearing, the magistrate judge denied plaintiffs’ motion. He concluded that the pages in question contained proprietary information that remained subject to the Protective Order under the “attorney’s eyes only” provision. Applying Texas state law regarding waiver of privilege, the magistrate judge found that ThermoTek had designated the proprietary information as confidential when it submitted it to the FDA; the FDA disclosure had occurred through no fault of ThermoTek; ThermoTek had taken reasonable steps, both with the FDA and with plaintiffs, to keep the information confidential; and ThermoTek had

taken immediate steps to remedy the mistaken disclosure once it occurred.⁵ The magistrate judge concluded:

Considerations of fairness counsel in favor of ruling that the proprietary information is not subject to public disclosure and should continue to be treated as Confidential under the Protective Order. The Court finds that all of the applicable factors weigh in favor of finding that waiver did not occur. The proprietary information shall remain subject to the Protective Order under the provision “for attorney’s eyes only.”

Oct. 2, 2012 Order 5.

Plaintiffs seek review of the magistrate judge’s order, maintaining that the court should reverse the order and compel ThermoTek to remove the restrictive designation of

⁵Specifically, the magistrate judge found that ThermoTek designated the proprietary information in the ThermoTek 510(k) as confidential before it submitted the form to the FDA; the FDA inadvertently failed to redact the proprietary information from the 510(k), as ThermoTek requested, and posted the entire 510(k), including the proprietary information, on the Internet; ThermoTek took reasonable precautions before it released the 510(k) to the FDA by marking the proprietary information as confidential; ThermoTek designated the proprietary information in the 510(k) as confidential and placed the proprietary information under the protection of the protective order marked “for attorneys eyes only”; ThermoTek neither released the proprietary information to the FDA nor to plaintiffs as unprotected; ThermoTek’s precautions to prevent disclosure were entirely reasonable; ThermoTek immediately asserted confidentiality under the protective order as soon as plaintiffs produced the publicly-obtained proprietary information during the deposition, which coincided with the time ThermoTek learned of a possible problem with the FDA’s disclosure; ThermoTek conducted an immediate investigation and required the FDA to correct its error by withdrawing the proprietary information from the FDA website; ThermoTek acted expeditiously in remedying the error; the proprietary information remained subject to the protective order at all times; and ThermoTek designated the proprietary information as confidential when it submitted the 510(k) to the FDA.

“confidential” for pages 41, 824-849, and 1373 of OPWIL0006036-6902. Ps. Obj. 1.⁶

II

This appeal is governed by Fed. R. Civ. P. 72(a), which provides, in relevant part, that “[t]he district judge . . . must . . . modify or set aside any part of the [magistrate judge’s] order that is clearly erroneous or is contrary to law.” “The clearly erroneous standard applies to the factual components of the magistrate judge’s decision.” *Lahr v. Fulbright & Jaworski, L.L.P.*, 164 F.R.D. 204, 208 (N.D. Tex. 1996) (Fitzwater, J.) (quoting *Smith v. Smith*, 154 F.R.D. 661, 665 (N.D. Tex. 1994) (Fitzwater, J.)) (internal quotation marks omitted). “The district court may not disturb a factual finding of the magistrate judge unless, although there is evidence to support it, the reviewing court is left with the definite and firm conviction that a mistake has been committed.” *Id.* (quoting *Smith*, 154 F.R.D. at 665) (internal quotation marks and brackets omitted). “If a magistrate judge’s account of the evidence is plausible in light of the record viewed in its entirety, a district judge may not reverse it.” *Id.* (quoting *Smith*, 154 F.R.D. at 665) (internal quotation marks omitted). The legal conclusions of the magistrate judge are reviewable *de novo*, and the district judge “reverses if the magistrate

⁶Plaintiffs failed to comply with N.D. Tex. Civ. R. 7.2(e) in briefing their objections. As required by Rule 72.1(d), plaintiffs included in an appendix some (although not all) of the materials on which they relied to support their objections. Under Rule 72.1(a), they were required to file a supporting brief that complies with Rule 7.2. Rule 7.2(e) provides: “[T]he party’s brief must include *citations to each page of the appendix* that supports each assertion that the party makes concerning any documentary or non-documentary materials on which the party relies[.]” *Id.* (emphasis added). Plaintiffs’ brief (and their reply brief) contains numerous citations to documents without citing the specific appendix page. Plaintiffs are reminded that they must comply with Rule 7.2(e) in any future briefing in this case to which the Rule applies.

judge erred in some respect in her legal conclusions.” *Id.* (citing *Smith*, 154 F.R.D. at 665). “[T]he abuse of discretion standard governs review of that vast area of . . . choice that remains to the [magistrate judge] who has properly applied the law to fact findings that are not clearly erroneous.” *Id.* (quoting *Smith*, 154 F.R.D. at 665) (alteration and ellipsis in original; internal quotation marks omitted). “When a party appeals a magistrate judge’s order, he must demonstrate how the order is reversible under the applicable standard of review—*de novo* for error of law, clear error for fact findings, or abuse of discretion for discretionary matters.” *Jefferson-Pilot Life Ins. Co. v. Bellows*, 2003 WL 21501904, at *1 (N.D. Tex. June 24, 2003) (Fitzwater, J.).

III

Plaintiffs maintain that the magistrate judge erred in concluding that ThermoTek did not waive the privileged nature of the Releasable Version, and that the document did not qualify for designation as “confidential” under the terms of the Protective Order once it was publically disclosed under FOIA. ThermoTek contends that the magistrate judge properly relied on and applied Texas privilege law to conclude that the FDA’s disclosure of the Releasable Version did not waive ThermoTek’s claim that the information is confidential.

The court agrees with plaintiffs that the magistrate judge erred in concluding that the documents in question qualified for designation as “confidential” under the terms of the Protective Order once they were publically disclosed, although the court reaches this conclusion on somewhat different reasoning. The issue in this dispute is not one of privilege and waiver of privilege. Instead, because the parties entered into a stipulated protective

order, the question is whether they intended that documents disclosed publically under circumstances such as occurred here could be designated as “confidential” under the Protective Order.⁷

“An agreed protective order may be viewed as a contract, and once parties enter an agreed protective order they are bound to its terms, absent good cause to modify or vacate the protective order.” *Paine v. City of Chicago*, 2006 WL 3065515, at *2 (N.D. Ill. Oct. 26, 2006) (citing *Kyles v. J.K. Guardian Sec. Servs.*, 2006 WL 2349238, at *8 (N.D. Ill. August 15, 2006)).⁸ “As with all contracts, the ultimate question is what was the parties’ mutual intent. The answer to that question is to be found within [the protective order’s] four corners, and not by reference to what might satisfy the purposes of one of the parties to it.” *Id.* (quoting *Autotech Techs. Ltd. P’ship v. Automationdirect.com, Inc.*, 2006 WL 1304949, at *4 (N.D. Ill. May 10, 2006) (brackets in original; internal quotation marks omitted).

The relevant parts of the Protective Order provide in the section on “*Definitions*”:⁹

⁷The court disagrees with ThermoTek’s contention that the issue in this appeal “is whether a direct competitor of ThermoTek can take advantage of the FDA’s inadvertent production to use ThermoTek’s confidential information to compete unfairly against ThermoTek.” ThermoTek Resp. 1. Instead, the question is whether plaintiffs have shown that the magistrate judge erred in upholding ThermoTek’s designation of the documents in question as “confidential.” The court’s decision addresses how these consolidated cases are to be litigated, not how information disclosed by the FDA can or cannot be used by a ThermoTek competitor.

⁸The court’s reliance on cases decided in the Northern District of Illinois is not misplaced. The court is unaware of contrary Fifth Circuit law, and the Protective Order was entered in the Northern District of Illinois before the case was transferred to this court.

⁹The protective order entered in 3:10-CV-2618-D contains similar provisions. *See, e.g.*, Apr. 20, 2011 Agreed Protective Order ¶ 17.

b. Information designated as “CONFIDENTIAL” is information concerning a person’s business operations, processes, technical, research, development information; engineering drawings, code or test data; commercial, financial, budgeting or accounting information; sales, revenue, margins, profits or cost of production information; marketing studies, performance data, and projections, business strategies, decisions, or negotiations; personnel compensation, evaluations, or other employment information, and information about affiliates, parents, subsidiaries, and third parties with whom the Parties to this action have had actual or potential business (other than customer) relationships, the disclosure of which is likely to harm that person’s competitive position, or the disclosure of which would contravene an obligation of confidentiality to a third person or to a Court.

* * *

d. Information should not be designated as “CONFIDENTIAL” or “CONFIDENTIAL - ATTORNEYS EYES ONLY” if it is disclosed in a printed publication, is known to the public, was known to the recipient without obligation of confidentiality before the producer disclosed it, or is or becomes known to the recipient by means not constituting a breach of this Order. Information should likewise not be designated as “CONFIDENTIAL” or “CONFIDENTIAL - ATTORNEYS EYES ONLY” if a person lawfully obtained it independently of this litigation.

Protective Order ¶¶ 2(b) and (d).¹⁰

The pertinent provisions of the Protective Order are written, not in terms of whether information is privileged, but whether confidential information has been disclosed. If it has

¹⁰The court has intentionally omitted the Protective Order’s definition of information that qualifies as “CONFIDENTIAL - ATTORNEYS EYES ONLY.” The parties agree that, despite the magistrate judge’s reference to “attorney’s eyes only,” the documents in question should (if designated at all) be designated as “confidential.” *See* ThermoTek Resp. 14-15; Ps. Reply Br. 1 n.1.

been disclosed in a printed publication, is known to the public, was known to the recipient without obligation of confidentiality before the producer disclosed it, is or has become known to the recipient by means not constituting a breach of the Protective Order, or a person lawfully obtains the information independently of this litigation, then it does not qualify for designation as “confidential.” *See* ¶ 2(d). Therefore, because the information in question was disclosed publically, and there is no indication that the information became known to plaintiffs by means that constituted a breach of the Protective Order, then regardless why the information was disclosed, it does not qualify under ¶ 2(d) of the Protective Order to be designated as “confidential.” The parties’ mutual intent, as reflected within the four corners of the Protective Order, does not include an exception for information that became public in error. They presumably knew how to include such a clause had this been their intention. For example, they included an exception for information that became known to the recipient by means constituting a breach of the Protective Order. And they opted in ¶ 6 of the Protective Order to invoke Fed. R. Evid. 502 with respect to the inadvertent disclosure of information claimed to be privileged or to qualify as work product.¹¹ But they did not include in the Protective Order any exception for the type of mistaken public disclosure that occurred here. There is an uncomplicated and ready answer to any concern that this ruling injures parties like ThermoTek whose documents become public through the fault of someone else (here, perhaps due to an error by a government agency): ThermoTek could have insisted that the

¹¹ThermoTek does not rely on ¶ 6 to argue that the documents in question are properly designated as “confidential.”

Protective Order include in a provision that covered this very type of situation, but it apparently did not. Accordingly, enforcing ¶ 2(d) as written, the court holds that the information in question does not qualify for “confidential” designation because it was publically disclosed.

The magistrate judge erred in denying plaintiffs’ motion to sustain and compel on the ground that ThermoTek had not waived its privilege to proprietary information. The order is reversed, plaintiffs’ motion to sustain their objection and to compel ThermoTek to withdraw its designation is granted, and this matter is remanded to the magistrate judge to address the remaining part of the motion in which plaintiffs seek sanctions.¹²

* * *

The court concludes for the reasons explained that the magistrate judge erred in denying Orthoflex’s motion to compel ThermoTek to withdraw its designation of a document as confidential. The magistrate judge’s October 2, 2012 order is therefore reversed, the motion to sustain plaintiffs’ objection and to compel ThermoTek to withdraw its designation is granted, and this matter is remanded to the magistrate judge to address plaintiffs’ request

¹²The court by remanding this unreachd portion of the motion is *not* suggesting that sanctions should be imposed. It is not the court’s role, however, to decide this question in the first instance.

for sanctions

SO ORDERED.

June 20, 2013.



SIDNEY A. FITZWATER
CHIEF JUDGE